Methotrexate Shared Care Agreement

For treatment of adults with rheumatoid arthritis and autoimmune rheumatic disease

SECONDARY CARE SECTION TO BE COMPLETED BY INITIATING CLINICIAN

Patient's Name: ..... NHS Number: .....

Date of Birth: ..... Date Treatment Started: .....

Copy of information given to patient ☐

Copy of agreement to general practitioner ☐

Name of Initiating Nurse Specialist / Doctor:

Consultant:

Speciality: RHEUMATOLOGY

Email: trauma.ortho@nhs.net

PRIMARY CARE SECTION TO BE COMPLETED BY GENERAL PRACTITIONER

I agree*/don't agree* to enter into a shared care arrangement for the treatment of the above patient with this medicine (*delete as appropriate)

GP Name: _____

Signature: _____ Date: .....

Once signed please detach this sheet and return to the email address shown above.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Extension:	Fax or e-mail address
Consultant Rheumatologists: **Dr Situnayake** **Dr. Situnayake** **Dr Elamanchi** **Dr DePablo** **Dr Prabu** **Dr Tosounidou** **Dr Baskar** **Dr Chandatre** **Dr McGrath**	01922 721172	Ext.7882 (secretary)	deva.situnayake@nhs.net srinivasa.elamanchi@nhs.net paola.de-pablo@nhs.net a.prabu@nhs.net stosounidou@nhs.net sangeetha.baskar@nhs.net priyankachandatre@nhs.net catherine.mcgrath@nhs.net
Rheumatology Nurse Specialists: **Sue Ward** **Marcia Daley**	01922 721172	Ext 7265 Bleep 8053	susan.ward31@nhs.neT marciadaley@nhs.net

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Hospital Pharmacy Dept: Jien Vyas	01922 721172	Ext. 7534	

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines ways in which the responsibilities for managing the prescribing of methotrexate in rheumatic diseases can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

Aspects of Care for which the Hospital Specialist is Responsible:

- Perform baseline tests (FBC, LFTs, U&E's, Creatinine, Chest X-ray).
- Discuss the benefits and side effects of treatment with the patient.
- Initiate and stabilise treatment with methotrexate. Recommend dose and timing of concomitant folic acid.
- Ask the GP whether he or she is willing to participate in shared care.
- Provide results of baseline tests and recommend frequency of monitoring to GP.
- Periodically review the patient's condition and communicate promptly with the GP when treatment is changed.
- Advise the GP on when to adjust the dose, stop treatment, or consult with specialist.
- Report adverse events to the MHRA and GP.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.

Aspects of Care for which the General Practitioner is responsible:

- Reply to the request for shared care as soon as practicable.
- Prescribe methotrexate at the dose recommended.
- Ensure compatibility with other concomitant medication.
- Ensure that the patient understands that dosing is at weekly intervals, and which warning symptoms to report.
- Monitor FBC, LFTs, U&E, and ESR at recommended frequencies, and refer if abnormal.
- Adjust the dose as advised by the specialist.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Withhold medication when prescribed Antibiotics. Do not co-prescribe with Trimethoprim
- Report adverse events to the specialist and MHRA.

Aspects of Care for which the Patient is responsible:

- Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- Have regular blood test at either the Hospital or G.P surgery.
- Attend for your review appointments to ensure you are being carefully monitored.
- Inform specialist or GP of other medication being taken, including over-the-counter products.
- Report any adverse effects or symptoms to the GP or specialist (Rheumatology Helpline 01922 721172 ext 7265).

Presentation and Availability

Tablets in strengths 2.5mg and 10mg – **please prescribe the 2.5mg tablets** to avoid the risk of confusion and potential overdose.

Subcutaneous Methotrexate Injection. (**Metoject pen**)

The hospital will be responsible for training the patients to self-administer via the Medical Day Care Unit. Once bloods and disease are stable, the GP will be responsible for prescribing the subcutaneous preparation. NB. If receiving subcutaneous methotrexate, a cytotoxic sharps bin will be prescribed on their first prescription. The patient will then need to apply to Walsall Council for collection and delivery of their subsequent Cytotoxic sharps bin on 01922 65 33 44. Option 1 – clinical waste. (They will need to complete an application form before collection and delivery can commence).

Dosage and Administration

All increases and dose adjustments will be done in Outpatients unless directions have been specified in the medical letter to the GP. All patients should be co-prescribed Folic acid at a minimum dose of 5mg weekly (24 hours before or 24 hours after Methotrexate) to minimise the risk of minor side effects.

Range	2.5 mgs to 25mgs **as a single dose once a week**
Starting dose	10-15mg per week
Titration	Dependent on tolerability and blood profile, as advised by Rheumatology team.
Folic Acid	Minimum dose of 5mgs weekly, to be taken 24 hours before or 24 hours after dose of methotrexate. Maximum Folic Acid dose is 5mgs daily, except for the day of methotrexate. **NOT TO BE TAKEN ON DAY OF METHOTREXATE.**
S/C injection	Pre-filled, single use device for subcutaneous injection available from 7.5mgs to 30mgs doses.(**Metoject pen device**)

Adverse Effects

Common non-life-threatening adverse effects of low-dose methotrexate are nausea, diarrhoea and stomatitis, headaches, drowsiness and rashes. The risk of minor adverse effects may be reduced by giving regular folic acid. Serious but rare side-effects include bone marrow suppression, hepatotoxicity and methotrexate pneumonitis. Annual influenza vaccination and pneumococcal vaccination is recommended.

Drug Interactions

- Methotrexate is extensively protein-bound and may be displaced by other protein-bound drugs (e.g. diuretics, salicylates, hypoglycaemics), with a potential for increased toxicity. Avoid concomitant use of drugs with nephrotoxic or hepatotoxic potential (including alcohol)
- **DO NOT co-prescribe trimethoprim or co-trimoxazole as severe bone marrow suppression may occur with concurrent use of methotrexate.**
- NSAIDs are not contraindicated with the above doses of methotrexate.

Contraindications

- Significant impairment of renal or hepatic function
- Active infectious disease or evidence of immunodeficiency syndrome(s)
- Serious cases of anaemia, leucopenia, or thrombocytopenia
- Patients with a known allergic hypersensitivity to methotrexate
- **Pregnancy or breast-feeding** - methotrexate is teratogenic and female patients of child-bearing age should be prescribed or offered contraception. Patients of either gender should use adequate contraception during treatment and wait for at least 3 months after discontinuation of methotrexate before trying to conceive. Women breastfeeding should not take methotrexate.

Monitoring

- Initial monitoring by Rheumatology team for the first 3 months - FBC, U&E, LFT, ESR, every 2 weeks until on a stable dose for 6 weeks then
- Once on a stable dose, monthly blood tests for 3 months,
- Thereafter blood tests at least every 12 weeks*
  *More frequent monitoring is appropriate in patients at higher risk of toxicity.

  Dose increases should be monitored by blood tests above every 2 weeks until on a stable dose for 6 weeks then revert back to previous schedule.

GP's responsible for: **Monitoring FBC, LFTs, U&E, CRP and ESR as per BSR Guidance.**

Action to be taken:

- **WBC <3.5x10^9/l** - withhold *until discussed* with Rheumatology team
- **Neutrophils <1.8x10^9/l** - withhold *until discussed* with Rheumatology team
- **Platelets <135x10^9/l** - withhold *until discussed* with Rheumatology team
- **>2-fold rise in ALT** (*from upper limit of reference range*) - withhold *until discussed* with Rheumatology team
- **Rash or oral ulceration** - withhold *until discussed* with Rheumatology team
- **New or increasing dyspnoea or cough** - withhold *until discussed* with Rheumatology team
- **MCV>105fl** - investigate and if B12 or folate low, start appropriate supplementation
- **Significant deterioration in renal function** - reduce dose and inform Rheumatology team
- **Abnormal bruising or sore throat** - withhold until FBC result available

Please note: in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance.

If the patient is unwell with abnormal results out-of-hours and the Rheumatology team is not available to discuss, STOP the drug and seek advice from the General Medical on-call team.

References

Prescribing and monitoring of DMARDs for inflammatory arthritis. Arthritis Research Council, 2005 http://www.arthritisresearchuk.org/shop/products/publications/information-for-medical-professionals/hands-on/series-4/ho8.aspx

BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017

National Patient Safety Agency. www.npsa.nhs.uk

Wyeth Pharmaceuticals. Methotrexate sodium tablets 2.5 mg. Summary of Product Characteristics, 2003.

Administering Subcutaneous Methotrexate for Inflammatory Arthritis Royal College of Nursing 2nd edition 2013
https://www.bspar.org.uk/DocStore/FileLibrary/PDFs/RCN%20Guidance%20for%20Administering%20Subcutaneous%20Methotrexate%20for%20Inflammatory%20Arthritis%20(Second%20Edition).pdf

BNSSG Joint Formulary DMARD Monitoring Advice Guidance
http://www.bnssgformulary.nhs.uk/Shared-Care-Protocols